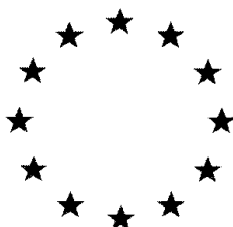


European Commission



VOLUME 3 – Annex B (PPP)

Laminarin

B.6 Toxicology and metabolism

Rapporteur Member State: The Netherlands

April 2016

**Draft Re-Assessment Report and Proposed decision of the Netherlands
prepared in the context of the possible renewal of laminarin under Regulation
(EC) 1107/2009**

Version history page

Date	Version history
April 2016	Initial RAR

TABLE OF CONTENTS – VOLUME 3 B.6

B.6	Toxicology and metabolism data	4
B.6.1	Acute toxicity.....	4
B.6.2	Dermal absorption	6
B.6.3	Available toxicological data relating to co-formulants.....	7
B.6.4	Exposure data.....	7
B.6.4.1	Operator exposure.....	8
B.6.4.2	Bystander and resident exposure.....	10
B.6.4.3	Worker exposure	11
B.6.5	Exposure and risk assessment.....	12
B.6.6	References relied on	14
Appendix 1:	Detailed exposure models.....	15
A 1.1	Operator, BBA model, tractor mounted field crop, no PPE	15
A 1.2	Operator, UK POEM, tractor mounted field crop, no PPE	16
A 1.3	Operator, BBA model, tractor mounted high crop, no PPE	17
A 1.4	Operator, UK POEM, tractor mounted high crop, no PPE	18
A 1.5	Operator, UK POEM, hand held low crop, no PPE	19
A 1.6	Operator, BBA model, hand held high crop, no PPE	20
A 1.7	Operator, UK POEM, hand held high crop, no PPE.....	21
A 1.8	Operator, Dutch greenhouse model, hand held high and low crop, no PPE	22
A 2.1	Bystander, EUROPOEM II	23
A 2.2	Bystander/resident, German guidance paper	24
A 2.3	Bystander/resident, UK method PSD Guidance	26
A 3.1	Worker, EUROPOEM II, re-entry field, no PPE	28
A 3.2	Worker, EUROPOEM II, re-entry greenhouse, no PPE	29

NOTES IN ADVANCE

The old representative formulation (PHYLIQ) is replaced by a new EU formulations (already registered): "Vacciplant Fruits et Légumes". This representative formulation, a soluble concentrate (SL) formulation, is used as elicitor of the crop's self defence mechanisms. The new representative uses differ from the old ones by the number of crops and the number of applications (20 applications maximum for Vacciplant Fruits et Légumes instead of 1 application with Phylig).

Vacciplant Fruits et Légumes contains 45 g/L laminarin and is intended for professional and amateur use on fruits and vegetables.

This section of the MCP dossier reviews the toxicological studies on the plant protection product Vacciplant Fruits et Légumes.

B.6 Toxicology and metabolism data

B.6.1 Acute toxicity

The acute toxicological studies were performed with the old representative formulation (PHYLIQ) which is replaced in the present submission by a new EU formulation (already registered): Vacciplant Fruits et Légumes.

The former formulation (PHYLIQ) was modified by replacement of several formulants (see Volume 4). Vacciplant Fruits et Légumes contains also a higher amount of active substance: 45 g/L laminarin instead of 37 g/L (nominal concentration).

Therefore, in order to avoid unnecessary animal experiments and because the former formulation (PHYLIQ) was not classified, it was decided to base the classification regarding acute toxicity on the conventional calculation method.

The applicant commented on the draft RAR, that there are recent (2014) toxicity studies with the Vacciplant representative formulation. These studies were not submitted in the original dossier (oral and dermal tox on rats, skin and eye irritation on rabbits, and LLNA study).

Applicant is aware that it was late in the AIR process and that they were not supposed to submit new studies at this stage, therefore applicant did not submit those five studies but wanted the RMS to be aware of their existence. Studies can be sent when requested; summaries were provided in February 2016.

There is no classification of the product following the above mentioned studies, except for LLNA study which is concluding to the product having a sensitisation potential (sensitizer) and to a H317 classification. Therefore proposed MSDS and labels for Vacciplant new formulation need to be modified accordingly if the studies are taken into account by RMS.

The RMS agrees that the new studies can be taken into account by individual Member States in the product authorization.

The results are presented below.

Oral

In order to avoid unnecessary animal experiments, the classification regarding acute oral toxicity is based on the conventional calculation method.

The results obtained by calculation enable to conclude that:

- in accordance with the criteria for classification, packaging and labeling of dangerous substances and preparations of the EEC Directives 67/548, 2001/59 and 1999/45, Vacciplant Fruits et Légumes must not be classified. No symbol or risk phrase is required.
- in accordance with Regulation (EC) No.1272/2008, Vacciplant Fruits et Légumes must not be classified. No signal word or hazard statement is required.

Dermal

In order to avoid unnecessary animal experiments, the classification regarding acute dermal toxicity is based on the conventional calculation method.

The results obtained by calculation enable to conclude that:

- in accordance with the criteria for classification, packaging and labeling of dangerous substances and preparations of the EEC Directives 67/548, 2001/59 and 1999/45, Vacciplant Fruits et Légumes must not be classified. No symbol or risk phrase is required.
- in accordance with Regulation (EC) No.1272/2008, Vacciplant Fruits et Légumes must not be classified. No signal word or hazard statement is required.

Inhalation

In order to avoid unnecessary animal experiments, the classification regarding acute inhalation toxicity is based on the conventional calculation method.

The results obtained by calculation enable to conclude that:

- in accordance with the criteria for classification, packaging and labeling of dangerous substances and preparations of the EEC Directives 67/548, 2001/59 and 1999/45, Vacciplant Fruits et Légumes must not be classified. No symbol or risk phrase is required.
- in accordance with Regulation (EC) No.1272/2008, Vacciplant Fruits et Légumes must not be classified. No signal word or hazard statement is required.

Skin irritation

In order to avoid unnecessary animal experiments, the classification regarding skin irritation is based on the conventional calculation method.

The results obtained by calculation enable to conclude that:

- in accordance with the criteria for classification, packaging and labeling of dangerous substances and preparations of the EEC Directives 67/548, 2001/59 and 1999/45, Vacciplant Fruits et Légumes must not be classified. No symbol or risk phrase is required.

- in accordance with Regulation (EC) No.1272/2008, Vacciplant Fruits et Légumes must not be classified. No signal word or hazard statement is required.

Eye irritation

In order to avoid unnecessary animal experiments, the classification regarding eye irritation is based on the conventional calculation method.

The results obtained by calculation enable to conclude that:

- in accordance with the criteria for classification, packaging and labeling of dangerous substances and preparations of the EEC Directives 67/548, 2001/59 and 1999/45, Vacciplant Fruits et Légumes must not be classified. No symbol or risk phrase is required.
- in accordance with Regulation (EC) No.1272/2008, Vacciplant Fruits et Légumes must not be classified. No signal word or hazard statement is required.

There was some confusion about one of the ingredients in a co-formulant; according to the ECHA inventory, around 70% of notifier's self-classification indicated H318. However, the recent study with the new Vacciplant FL formulation reveal only slight eye irritation, which had resolved at 24h, hence no classification appears to be needed for Vacciplant FL.

The applicant is requested to submit this eye irritation study.

Skin sensitisation

In order to avoid unnecessary animal experiments, the classification regarding skin sensitisation was initially based on the conventional calculation method.

However, the applicant indicated that recent studies with the new formulation are available, and the LLNA study indicated that the new product has a sensitisation potential (sensitizer) and should be labelled with H317. The proposed MSDS and labels for Vacciplant new formulation need to be modified accordingly.

The applicant is requested to submit this LLNA study.

Supplementary studies on the plant protection product

No studies provided nor needed.

Supplementary studies for the combination of plant protection products

No studies in combination with other plant protection products are necessary based on the profile of Vacciplant Fruits et Légumes.

B.6.2 Dermal absorption

No study was performed to determine the dermal absorption values of Laminarin. In absence of study, the dermal absorption is considered to be 10%, as a worst-case value, according to the Review

Report for the active substance laminarin (SANCO/10488/04-rev.3, 04/10/2004). This is based on the high molecular weight of the active substance (3240 – 4860 g/mol), and its log P_{ow} (-1.6 at 20°C).

This default of 10% for dermal absorption is in accordance with EFSA Guidance on dermal absorption (EFSA Journal 2013; 10(4):2665).

B.6.3 Available toxicological data relating to co-formulants

MSDSs are provided for the co-formulants.

B.6.4 Exposure data

No reference values were allocated during the approval (Annex I inclusion) of laminarin in 2005. The applicant proposes to use the value of 1000 mg/kg bw/d for setting an AOEL. Applying an assessment factor of 100 leads to an AOEL of 10 mg/kg bw/d. This value will be used for the estimation of operator exposure, as also no AOEL is proposed by the RMS.

Product information

Product: Vacciplant Fruits et Légumes
 Purpose: Elicitor
 Active substance (a.s.): laminarin
 Product type: soluble concentrate (SL)
 Package size: 1L (42 mm neck), 5L (63 mm neck)

Table 6.4-1 describes the critical use patterns that has been defined following of the individual GAPs for each crop.

Table 6.4-1 Summary of critical use (i.e. worst case)

Application equipment	Representative Crop	Max Application rate (L product/ha)	Max Application rate (kg a.s./ha)	Minimum Spray dilution (L/ha)	Number applications	Worst case for
Tractor mounted, low crop	Tomato, aubergine, pepper	3	0.135	500	7 (BBCH 10-89)	Operator
Tractor mounted, high crop	Vine	2	0.090	100	10 (BBCH 11-89)	Operator, worker bystander/resident
Handheld, low crop	aubergine	3	0.135	500	7 (BBCH 10-89)	Operator
Handheld, high crop	Vine	2	0.090	100	10 (BBCH 11-89)	Operator
Greenhouse	Tomato, aubergine, pepper	3	0.135	500	7 (BBCH 10-89)	Operator, worker

B.6.4.1 Operator exposure

Estimations of potential operator exposure for the formulation Vacciplant Fruits et Légumes are made for the intended critical uses described in table 6.4-1 and the following predictive models:

- Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection); Mitteilungen aus der Biologischen Bundesanstalt, Heft 277, Berlin 1992 (“German model”)
- Revised UK POE Model, UK Predictive Operator Exposure Model (POEM): Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 7 of 2008 (“UK POEM”)
- Dutch Greenhouse model, Van Golstein Brouwes, Y.G.C., Marquart, J. and Van Hemmen, J.J. 1996 Assessment of occupational exposure to pesticides in agriculture. Part IV. Protocol for the use of generic exposure data. TNO Nutrition and Food Research Institute, The Netherlands. TNO Report V 96.120 (“Dutch Greenhouse model”)

For amateur use, the operator risk assessment for handheld and greenhouse applications without PPE will be used as a worst case.

The exposure estimations were compared to the Acceptable Operator Exposure Level of 10 mg/kg bw/day (see Volume 1, level 2, point 2.6.13). For the dermal absorption a value of 10% is used for the concentrate and spray dilution (see B.6.2). To account for amateur uses as well, a more worst case body weight of 60 kg is used for the operator risk assessment.

B.6.4.1.1 Estimation of operator exposure without personal protective equipment

The input parameters that were applied in the models for the operator exposure estimation are described in Table B.6.4.1.1-1 to B.6.4.1.1-3.

Table B.6.4.1.1-1 Input parameter in the German model

Application method	Input parameter
Tractor-mounted sprayer, field crops	Treated area: 20 ha/day Max. dose rate: 0.135 kg laminarin/ha Operator body weight: 60* kg
Tractor-mounted sprayer, high crops	Treated area: 8 ha/day Max. dose rate: 0.090 kg laminarin /ha Operator body weight: 60* kg
Hand-held application, high crops	Treated area: 1 ha/day Max. dose rate: 0.090 kg laminarin /ha Operator body weight: 60* kg

* In the German model, a body weight of 70 kg is used for the professional operator. To account for amateur uses as well, a more worst case body weight of 60 kg is used for the risk assessment.

Table B.6.4.1.1-2 Input parameter in UK POEM

Application method	Input parameter
Tractor-mounted sprayer, field crops	Treated area/duration: 50 ha/day, 6 hours Max. dose rate: 0.135 kg laminarin /ha Spray volume: 500 L/ha Operator body weight: 60 kg
Tractor-mounted sprayer, high crops	Treated area/duration: 15 ha/day, 6 hours Max. dose rate: 0.090 kg laminarin /ha Spray volume: 100 L/ha Operator body weight: 60 kg
Hand-held application, field crops	Treated area/duration: 1 ha/day, 6 hours Max. dose rate: 0.135 kg laminarin /ha Spray volume: 500 L/ha Operator body weight: 60 kg
Hand-held application, high crops	Treated area/duration: 1 ha/day, 6 hours Max. dose rate: 0.090 kg laminarin /ha Spray volume: 100 L/ha Operator body weight: 60 kg

Table B.6.4.1.1-3 Input parameter in Dutch Greenhouse model

Application method	Input parameter
Greenhouse	Treated area/duration: 1 ha/day Max. dose rate: 0.135 kg laminarin /ha Operator body weight: 60* kg

* In the Dutch greenhouse model, a body weight of 70 kg is used for the professional operator. To account for amateur uses as well, a more worst case body weight of 60 kg is used for the risk assessment.

The operator exposure estimates assuming that no protective clothing is worn are summarized in Table B.6.4.1.1-4. The detailed calculator spreadsheets are included in Appendix 1, A 1.1 - A 1.8.

Table B.6.4.1.1-4 Exposure prediction and risk assessment without PPE

Application method	Model	Total systemic exposure (mg/kg bw/day) ¹	% of AOEL
Tractor-mounted sprayer, field crop	German model	0.02	<1
	UK POEM	0.13	1
Tractor-mounted sprayer, high crop	German model	0.02	<1
	UK POEM	0.21	2
Hand-held application, field crops	UK POEM	0.07	<1
Hand-held application, high crops	German model	0.04	<1

	UK POEM	0.14	1
Greenhouse	Dutch Greenhouse model	0.04	<1

¹ Systemic exposure based on dermal absorption of 10% for mixing and loading and 10% for application of Vacciplant Fruits et Légumes, and an AOEL of 10 mg/kg bw/d for the active substance laminarin.

Conclusion

The model estimates show that for the intended use of the formulation Vacciplant Fruits et Légumes the predicted systemic exposure for the unprotected operator is maximally 2%.

B.6.4.1.2 Estimation of operator exposure with personal protective equipment

Since the risk assessments performed indicate that the health-based limit value (AOEL) will not be exceeded under practical conditions of use, studies to provide field data on operator exposure to Vacciplant Fruits et Légumes were not considered to be necessary and therefore were not carried out.

B.6.4.2 Bystander and resident exposure

Estimations of potential bystander and resident exposure for the formulation Vacciplant Fruits et Légumes are made for the intended critical uses described in table 6.4-1.

The following predictive model will be used for the professional bystander:

- EUROPOEM II

Exposure of non-professional bystanders and residents is made using:

- the German guidance paper of BfR and
- the UK guidance document of PSD (Bystander exposure guidance –final version.pdf, 2008).

The German guidance paper has been published in the Journal of Consumer Protection and Food Safety (JVL 3 (2008), pp 272-281). The UK guidance document summarises measurements of bystander exposure during UK field crop spraying and orchard spraying applications which have been reported, respectively, by Lloyd and Bell, 1983 and by Lloyd *et al.*, 1987.

The risk assessment for bystander and resident exposure to Vacciplant Fruits et Légumes will be made considering the worst case in-field intended uses only:

- broadcast air-assisted sprayer,

For the bystander and resident risk assessment, the same end points as for operator exposure will be considered:

the exposure estimations are compared to the Acceptable Operator Exposure Level of 10 mg/kg bw/day (see Volume 1, level 2, point 2.6.13). For the dermal absorption a value of 10% is used for the concentrate and spray dilution (see B.6.2).

The bystander/resident exposure estimates assuming that no protective clothing is worn are summarized in Table B.6.4.2-1. The detailed calculator spreadsheets are included in Appendix 1, A 2.1 - A 2.3.

Table B.6.4.2-1 Bystander/resident exposure prediction and risk assessment

Route		Estimated internal exposure (mg/day)	Systemic AEL (mg/day)	% AOEL
<i>Bystander (professional) exposure during application in representative crops according to EUROPOEM II</i>				
Adult	Total	0.158	600.00	0.03%
<i>Bystander exposure during application in representative crops according to the German guidance</i>				
Child	Total	0.0153	161.50	0.01%
Adult	Total	0.0724	600.00	0.01%
<i>Resident exposure during application in all representative crops according to the German guidance</i>				
Child	Total	0.0149	161.50	0.01%
Adult	Total	0.0261	600.00	<0.01%
<i>Bystander exposure during application in representative crops according to the UK guidance</i>				
Adult	Total	0.0095	600.00	<0.01%
<i>Resident exposure during application in representative crops according to the UK guidance</i>				
Child	Respiratory	0.0083	150.00	0.01%
	Dermal+Oral	0.0014	150.00	<0.01%

Conclusion

The model estimates show that for the intended use of the formulation Vacciplant Fruits et Légumes the predicted systemic exposure for the unprotected bystander (adults) and residents (adults and children) is maximally 0.03%.

B.6.4.3 Worker exposure

Estimations of potential worker exposure for the formulation Vacciplant Fruits et Légumes are made for the intended critical uses described in table 6.4-1 and the following predictive models:

- EUROPOEM II

The exposure estimations were compared to the Acceptable Operator Exposure Level of 10 mg/kg bw/day (see Volume 1, level 2, point 2.6.13). For the dermal absorption a value of 10% is used for the concentrate and spray dilution (see B.6.2).

The input parameters that were applied in the models for the worker exposure estimation are:

DFR (Dislodgeable Foliar Residues):	3 µg/cm ² *kg applied a.s.
TC (Transfer coefficient):	4500 cm ² /h (tomato, vertical growth) 10000 cm ² /h (vines)
ED (Exposition duration):	8 h/day (normal working day)
AR (application rate):	7 times 0.135 kg as/ha (tomato)

	10 times 0.090 kg as/ha (vines)
Dermal absorption (DA)	10%, (un)diluted formulation
b.w. (body weight):	60 kg
P (Penetration coefficient):	100 % no PPE

The worker exposure estimates assuming that no protective clothing is worn are summarized in Table B.6.4.3-1. The detailed calculator spreadsheet are included in Appendix 1, A 3.1- A 3.2

Table B.6.4.3-1 Exposure prediction and risk assessment without PPE

Application method	Model	Total systemic exposure (mg/kg bw/day) ¹	% of AOEL
Field, vines	EUROPOEM II	0.36	4
Greenhouse, tomato	EUROPOEM II	0.18	2

¹ Systemic exposure based on dermal absorption of 10% for mixing and loading and 10% for application of Vacciplant Fruits et Légumes, and an AOEL of 10 mg/kg bw/d for the active substance laminarin.

Conclusion

The model estimates show that for the intended use of the formulation Vacciplant Fruits et Légumes the predicted systemic exposure for the unprotected worker is maximally 4%.

B.6.5 Exposure and risk assessment

Operator

- Using the German model, safe uses were identified for operators, *without* PPE, for:
 - ☐ Mechanical downward spraying on lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi
 - ☐ Mechanical upward spraying on apples, pear, vine, strawberry, tomato, aubergine, pepper, and kiwi
 - ☐ Manual upward spraying on apples, pear, vine, strawberry, tomato, aubergine, pepper, and kiwi
- Using UK-POEM, safe uses were identified for operators, *without* PPE, for:
 - ☐ Mechanical downward spraying on lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi
 - ☐ Mechanical upward spraying on apples, pear, vine, strawberry, tomato, aubergine, pepper, and kiwi
 - ☐ Manual downward spraying on lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi
 - ☐ Manual upward spraying on apples, pear, vine, strawberry, tomato, aubergine, pepper, and kiwi
- Using the Dutch-90th greenhouse model, safe uses were identified for operators, *without* PPE, for:
 - ☐ Manual spraying on lettuce, strawberry, tomato, aubergine, pepper, cucumber, zucchini

Bystander and residents

Safe uses for bystanders and residents were identified for exposure during spraying on apples, pear, vine, lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi, using EUROPOEM II, the German guidance paper and the UK PSD guidance document.

Worker

Safe uses for workers *without* PPE were identified during re-entry exposure in apples, pear, vine, lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi, using *the EUROPOEM II 2002 model (90th percentile)*.

B.6.6 References relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

No studies submitted.

Appendix 1: Detailed exposure models

A 1.1 Operator, BBA model, tractor mounted field crop, no PPE

Estimation of operator exposure: German model

Input parameters considered for the estimation of operator exposure:

Formulation type:	Liquid	Application technique:	Field Crops, Tractor Mounted (FCTM)
Application rate (AR):	0.135 kg	Dermal hands m/l (D_{M(H)}):	2.4 mg/person/kg a.s.
Area treated per day (A):	20 ha	Dermal hands appl. (D_{AG(H)}):	0.38 mg/person/kg a.s.
Dermal absorption (DA):	10 % (concentr.) 10 % (dilution)	Dermal body appl. (D_{AG(B)}):	1.6 mg/person/kg a.s.
Inhalation absorption (IA):	100 %	Dermal head appl. (D_{AG(C)}):	0.06 mg/person/kg a.s.
Body weight (BW):	60 kg/person	Inhalation m/l (I_M):	0.0006 mg/person/kg a.s.
AOEL	10 mg/kg bw/d	Inhalation appl. (I_A):	0.001 mg/person/kg a.s.

Operator exposure towards laminarin			
Without PPE		With PPE	
Operators: Systemic dermal exposure after application in tomato, aubergine, pepper			
Dermal exposure during mixing/loading			
Hands		Hands	
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$ (2.4 x 0.135 x 20 x 10%) / 60		$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^1 \times DA) / BW$ (2.4 x 0.135 x 20 x 1 x 10%) / 60	
External dermal exposure	6.48 mg/person	External dermal exposure	6.48 mg/person
External dermal exposure	0.108 mg/kg bw/d	External dermal exposure	0.108 mg/kg bw/d
Systemic dermal exposure	0.010800 mg/kg bw/d	Systemic dermal exposure	0.010800 mg/kg bw/d
Dermal exposure during application			
Hands		Hands	
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$ (0.38 x 0.135 x 20 x 10%) / 60		$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^1 \times DA) / BW$ (0.38 x 0.135 x 20 x 1 x 10%) / 60	
External dermal exposure	1.026 mg/person	External dermal exposure	1.026 mg/person
External dermal exposure	0.0171 mg/kg bw/d	External dermal exposure	0.0171 mg/kg bw/d
Systemic dermal exposure	0.001710 mg/kg bw/d	Systemic dermal exposure	0.001710 mg/kg bw/d
Body		Body	
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$ (1.6 x 0.135 x 20 x 10%) / 60		$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^2 \times DA) / BW$ (1.6 x 0.135 x 20 x 1 x 10%) / 60	
External dermal exposure	4.32 mg/person	External dermal exposure	4.32 mg/person
External dermal exposure	0.072 mg/kg bw/d	External dermal exposure	0.072 mg/kg bw/d
Systemic dermal exposure	0.007200 mg/kg bw/d	Systemic dermal exposure	0.007200 mg/kg bw/d
Head		Head	
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$ (0.06 x 0.135 x 20 x 10%) / 60		$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE^3 \times DA) / BW$ (0.06 x 0.135 x 20 x 1 x 10%) / 60	
External dermal exposure	0.162 mg/person	External dermal exposure	0.162 mg/person
External dermal exposure	0.0027 mg/kg bw/d	External dermal exposure	0.0027 mg/kg bw/d
Systemic dermal exposure	0.000270 mg/kg bw/d	Systemic dermal exposure	0.000270 mg/kg bw/d
Total systemic dermal exposure: $SDE_0 = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		Total systemic dermal exposure: $SDE_0 = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$	
Total external dermal exposure	11.988 mg/person	Total external dermal exposure	11.988 mg/person
Total external dermal exposure	0.1998 mg/kg bw/d	Total external dermal exposure	0.1998 mg/kg bw/d
Total systemic dermal exposure	0.01998 mg/kg bw/d	Total systemic dermal exposure	0.01998 mg/kg bw/d
Operators: Systemic inhalation exposure after application in tomato, aubergine, pepper			
Inhalation exposure during mixing/loading			
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$ (0.0006 x 0.135 x 20 x 100%) / 60		$SIE_{OM} = (I_M \times AR \times A \times PPE^4 \times IA) / BW$ (0.0006 x 0.135 x 20 x 1 x 100%) / 60	
External inhalation exposure	0.00162 mg/person	External inhalation exposure	0.00162 mg/person
External inhalation exposure	0.000027 mg/kg bw/d	External inhalation exposure	0.000027 mg/kg bw/d
Systemic inhalation exposure	0.000027 mg/kg bw/d	Systemic inhalation exposure	0.000027 mg/kg bw/d
Inhalation exposure during application			
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$ (0.001 x 0.135 x 20 x 100%) / 60		$SIE_{OA} = (I_A \times AR \times A \times PPE^4 \times IA) / BW$ (0.001 x 0.135 x 20 x 1 x 100%) / 60	
External inhalation exposure	0.0027 mg/person	External inhalation exposure	0.0027 mg/person
External inhalation exposure	0.000045 mg/kg bw/d	External inhalation exposure	0.000045 mg/kg bw/d
Systemic inhalation exposure	0.000045 mg/kg bw/d	Systemic inhalation exposure	0.000045 mg/kg bw/d
Total systemic inhalation exposure: $SIE_0 = SIE_{OM} + SIE_{OA}$		Total systemic inhalation exposure: $SIE_0 = SIE_{OM} + SIE_{OA}$	
Total external inhalation exposure	0.004320 mg/person	Total external inhalation exposure	0.004320 mg/person
Total external inhalation exposure	0.000072 mg/kg bw/d	Total external inhalation exposure	0.000072 mg/kg bw/d
Total systemic inhalation exposure	0.000072 mg/kg bw/d	Total systemic inhalation exposure	0.000072 mg/kg bw/d
Total systemic exposure: $SE_0 = SDE_0 + SIE_0$		Total systemic exposure: $SE_0 = SDE_0 + SIE_0$	
Total systemic exposure	1.20312 mg/person	Total systemic exposure	1.20312 mg/person
Total systemic exposure	0.020052 mg/kg bw/d	Total systemic exposure	0.020052 mg/kg bw/d
% of AOEL	0.2 %	% of AOEL	0.2 %

A 1.2 Operator, UK POEM, tractor mounted field crop, no PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Product	Vacciplant Fruits et Légumes	Active substance	laminarin
Formulation type	water-based	a.s. concentration	45 mg/ml
Dermal absorption from product	10 %	Dermal absorption from spray	10 %
Container	1 litre any closure		
PPE during mix/loading	None	PPE during application	None
Dose	3 l/ha	Work rate/day	50 ha
Application volume	500 l/ha	Duration of spraying	6 h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	3 litres product/ha
Work rate	50 ha/day
Number of operations	150
Hand contamination	1.5 ml/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to formulation	1.5 ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Application volume	500 spray/ha		
Volume of surface contamination	10 ml/h		
Distribution	Hands	Trunk	Legs
	65%	10%	25%
Clothing	None	Permeable	Permeable
Penetration	100%	5%	15%
Dermal exposure	6.5	0.05	0.375 ml/h
Duration of exposure	6 h		
Total dermal exposure to spray	41.55 ml/day		

ABSORBED DERMAL DOSE

	Mix/load	Application
Dermal exposure	1.5 ml/day	41.55 ml/day
Concen. of a.s. product or spray	45 mg/ml	0.27 mg/ml
Dermal exposure to a.s.	67.5 mg/day	11.2185 mg/day
Percent absorbed	10 %	10 %
Absorbed dose	6.75 mg/day	1.12185 mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	0.27 mg/ml
Inhalation exposure to a.s.	0.0162 mg/day
Percent absorbed	100 %
Absorbed dose	0.0162 mg/day

PREDICTED EXPOSURE

Total absorbed dose	7.88805 mg/day
Operator body weight	60 kg
Operator exposure	0.1314675 mg/kg bw/day

A 1.3 Operator, BBA model, tractor mounted high crop, no PPE**Estimation of operator exposure: German model**

Input parameters considered for the estimation of operator exposure:

Formulation type:	Liquid	Application technique:	High Crops, Tractor Mounted (HCTM)
Application rate (AR):	0.09 kg	Dermal hands m/l (D_{M(H)}):	2.4 mg/person/kg a.s.
Area treated per day (A):	8 ha	Dermal hands appl. (D_{AG(H)}):	0.7 mg/person/kg a.s.
Dermal absorption (DA):	10 % (concentr.)	Dermal body appl. (D_{AG(B)}):	9.6 mg/person/kg a.s.
	10 % (dilution)	Dermal head appl. (D_{AG(C)}):	1.2 mg/person/kg a.s.
Inhalation absorption (IA):	100 %	Inhalation m/l (I_M):	0.0006 mg/person/kg a.s.
Body weight (BW):	60 kg/person	Inhalation appl. (I_A):	0.018 mg/person/kg a.s.
AOEL	10 mg/kg bw/d		

Operator exposure towards laminarin			
Without PPE		With PPE	
Operators: Systemic dermal exposure after application in vine			
Dermal exposure during mixing/loading			
Hands		Hands	
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$		$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^1 \times DA) / BW$	
$(2.4 \times 0.09 \times 8 \times 10\%) / 60$		$(2.4 \times 0.09 \times 8 \times 1 \times 10\%) / 60$	
External dermal exposure	1.728 mg/person	External dermal exposure	1.728 mg/person
External dermal exposure	0.0288 mg/kg bw/d	External dermal exposure	0.0288 mg/kg bw/d
Systemic dermal exposure	0.002880 mg/kg bw/d	Systemic dermal exposure	0.002880 mg/kg bw/d
Dermal exposure during application			
Hands		Hands	
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$		$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^1 \times DA) / BW$	
$(0.7 \times 0.09 \times 8 \times 10\%) / 60$		$(0.7 \times 0.09 \times 8 \times 1 \times 10\%) / 60$	
External dermal exposure	0.504 mg/person	External dermal exposure	0.504 mg/person
External dermal exposure	0.0084 mg/kg bw/d	External dermal exposure	0.0084 mg/kg bw/d
Systemic dermal exposure	0.000840 mg/kg bw/d	Systemic dermal exposure	0.000840 mg/kg bw/d
Body		Body	
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$		$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^2 \times DA) / BW$	
$(9.6 \times 0.09 \times 8 \times 10\%) / 60$		$(9.6 \times 0.09 \times 8 \times 1 \times 10\%) / 60$	
External dermal exposure	6.912 mg/person	External dermal exposure	6.912 mg/person
External dermal exposure	0.1152 mg/kg bw/d	External dermal exposure	0.1152 mg/kg bw/d
Systemic dermal exposure	0.011520 mg/kg bw/d	Systemic dermal exposure	0.011520 mg/kg bw/d
Head		Head	
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$		$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE^3 \times DA) / BW$	
$(1.2 \times 0.09 \times 8 \times 10\%) / 60$		$(1.2 \times 0.09 \times 8 \times 1 \times 10\%) / 60$	
External dermal exposure	0.864 mg/person	External dermal exposure	0.864 mg/person
External dermal exposure	0.0144 mg/kg bw/d	External dermal exposure	0.0144 mg/kg bw/d
Systemic dermal exposure	0.001440 mg/kg bw/d	Systemic dermal exposure	0.001440 mg/kg bw/d
Total systemic dermal exposure: $SDE_0 = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		Total systemic dermal exposure: $SDE_0 = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$	
Total external dermal exposure	10.008 mg/person	Total external dermal exposure	10.008 mg/person
Total external dermal exposure	0.1668 mg/kg bw/d	Total external dermal exposure	0.1668 mg/kg bw/d
Total systemic dermal exposure	0.01668 mg/kg bw/d	Total systemic dermal exposure	0.01668 mg/kg bw/d
Operators: Systemic inhalation exposure after application in vine			
Inhalation exposure during mixing/loading			
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$		$SIE_{OM} = (I_M \times AR \times A \times PPE^4 \times IA) / BW$	
$(0.0006 \times 0.09 \times 8 \times 100\%) / 60$		$(0.0006 \times 0.09 \times 8 \times 1 \times 100\%) / 60$	
External inhalation exposure	0.000432 mg/person	External inhalation exposure	0.000432 mg/person
External inhalation exposure	0.0000072 mg/kg bw/d	External inhalation exposure	0.0000072 mg/kg bw/d
Systemic inhalation exposure	0.000007 mg/kg bw/d	Systemic inhalation exposure	0.000007 mg/kg bw/d
Inhalation exposure during application			
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$		$SIE_{OA} = (I_A \times AR \times A \times PPE^4 \times IA) / BW$	
$(0.018 \times 0.09 \times 8 \times 100\%) / 60$		$(0.018 \times 0.09 \times 8 \times 1 \times 100\%) / 60$	
External inhalation exposure	0.01296 mg/person	External inhalation exposure	0.01296 mg/person
External inhalation exposure	0.000216 mg/kg bw/d	External inhalation exposure	0.000216 mg/kg bw/d
Systemic inhalation exposure	0.000216 mg/kg bw/d	Systemic inhalation exposure	0.000216 mg/kg bw/d
Total systemic inhalation exposure: $SIE_0 = SIE_{OM} + SIE_{OA}$		Total systemic inhalation exposure: $SIE_0 = SIE_{OM} + SIE_{OA}$	
Total external inhalation exposure	0.013392 mg/person	Total external inhalation exposure	0.013392 mg/person
Total external inhalation exposure	0.000223 mg/kg bw/d	Total external inhalation exposure	0.000223 mg/kg bw/d
Total systemic inhalation exposure	0.000223 mg/kg bw/d	Total systemic inhalation exposure	0.000223 mg/kg bw/d
Total systemic exposure: $SE_0 = SDE_0 + SIE_0$		Total systemic exposure: $SE_0 = SDE_0 + SIE_0$	
Total systemic exposure	1.01419 mg/person	Total systemic exposure	1.01419 mg/person
Total systemic exposure	0.016903 mg/kg bw/d	Total systemic exposure	0.016903 mg/kg bw/d
% of AOEL	0.2 %	% of AOEL	0.2 %

A 1.4 Operator, UK POEM, tractor mounted high crop, no PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Product	Vacciplant Fruits et Légumes	Active substance	laminarin
Formulation type	water-based	a.s. concentration	45 mg/ml
Dermal absorption from product	10 %	Dermal absorption from spray	10 %
Container	1 litre any closure		
PPE during mix/loading	None	PPE during application	None
Dose	2 l/ha	Work rate/day	15 ha
Application volume	100 l/ha	Duration of spraying	6 h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	2 litres product/ha
Work rate	15 ha/day
Number of operations	30
Hand contamination	0.3 ml/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to formulation	0.3 ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha		
Application volume	100 spray/ha		
Volume of surface contamination	400 ml/h		
Distribution	Hands	Trunk	Legs
	10%	65%	25%
Clothing	None	Permeable	Permeable
Penetration	100%	2%	5%
Dermal exposure	10	5.2	5 ml/h
Duration of exposure	6 h		
Total dermal exposure to spray	121.2 ml/day		

ABSORBED DERMAL DOSE

	Mix/load	Application
Dermal exposure	0.3 ml/day	121.2 ml/day
Concen. of a.s. product or spray	45 mg/ml	0.9 mg/ml
Dermal exposure to a.s.	13.5 mg/day	109.08 mg/day
Percent absorbed	10 %	10 %
Absorbed dose	1.35 mg/day	10.908 mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.05 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	0.9 mg/ml
Inhalation exposure to a.s.	0.27 mg/day
Percent absorbed	100 %
Absorbed dose	0.27 mg/day

PREDICTED EXPOSURE

Total absorbed dose	12.528 mg/day
Operator body weight	60 kg
Operator exposure	0.2088 mg/kg bw/day

A 1.5 Operator, UK POEM, hand held low crop, no PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Product	Vacciplant Fruits et Légumes	Active substance	laminarin
Formulation type	water-based	a.s. concentration	45 mg/ml
Dermal absorption from product	10 %	Dermal absorption from spray	10 %
Container	1 litre any closure		
PPE during mix/loading	None	PPE during application	None
Dose	3 l/ha	Work rate/day	0.8 ha
Application volume	500 l/ha	Duration of spraying	6 h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	3 litres product/ha
Work rate	0.8 ha/day
Number of operations	27
Hand contamination	0.27 ml/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to formulation	0.27 ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Hand-held sprayer (15 l tank): hydraulic nozzles. Outdoor, low level target		
Application volume	500 spray/ha		
Volume of surface contamination	50 ml/h		
Distribution	Hands	Trunk	Legs
	25%	25%	50%
Clothing	None	Permeable	Permeable
Penetration	100%	20%	18%
Dermal exposure	10	2.5	4.5 ml/h
Duration of exposure	6 h		
Total dermal exposure to spray	102 ml/day		

ABSORBED DERMAL DOSE

	Mix/load	Application
Dermal exposure	0.27 ml/day	102 ml/day
Concen. of a.s. product or spray	45 mg/ml	0.27 mg/ml
Dermal exposure to a.s.	12.15 mg/day	27.54 mg/day
Percent absorbed	10 %	10 %
Absorbed dose	1.215 mg/day	2.754 mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.02 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	0.27 mg/ml
Inhalation exposure to a.s.	0.0324 mg/day
Percent absorbed	100 %
Absorbed dose	0.0324 mg/day

PREDICTED EXPOSURE

Total absorbed dose	4.0014 mg/day
Operator body weight	60 kg
Operator exposure	0.06669 mg/kg bw/day

A 1.6 Operator, BBA model, hand held high crop, no PPE**Estimation of operator exposure: German model**

Input parameters considered for the estimation of operator exposure:

Formulation type:	Liquid	Application technique:	High Crops, Hand Held (HCHH)
Application rate (AR):	0.09 kg	Dermal hands m/l (D_{M(H)}):	205 mg/person/kg a.s.
Area treated per day (A):	1 ha	Dermal hands appl. (D_{AG(H)}):	10.6 mg/person/kg a.s.
Dermal absorption (DA):	10 % (concentr.)	Dermal body appl. (D_{AG(B)}):	25 mg/person/kg a.s.
	10 % (dilution)	Dermal head appl. (D_{AG(C)}):	4.8 mg/person/kg a.s.
Inhalation absorption (IA):	100 %	Inhalation m/l (I_M):	0.05 mg/person/kg a.s.
Body weight (BW):	60 kg/person	Inhalation appl. (I_A):	0.3 mg/person/kg a.s.
AOEL	10 mg/kg bw/d		

Operator exposure towards laminarin			
Without PPE		With PPE	
Operators: Systemic dermal exposure after application in vine			
Dermal exposure during mixing/loading			
Hands		Hands	
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$		$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{-1} \times DA) / BW$	
$(205 \times 0.09 \times 1 \times 10\%) / 60$		$(205 \times 0.09 \times 1 \times 1 \times 10\%) / 60$	
External dermal exposure	18.45 mg/person	External dermal exposure	18.45 mg/person
External dermal exposure	0.3075 mg/kg bw/d	External dermal exposure	0.3075 mg/kg bw/d
Systemic dermal exposure	0.030750 mg/kg bw/d	Systemic dermal exposure	0.030750 mg/kg bw/d
Dermal exposure during application			
Hands		Hands	
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$		$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^{-1} \times DA) / BW$	
$(10.6 \times 0.09 \times 1 \times 10\%) / 60$		$(10.6 \times 0.09 \times 1 \times 1 \times 10\%) / 60$	
External dermal exposure	0.954 mg/person	External dermal exposure	0.954 mg/person
External dermal exposure	0.0159 mg/kg bw/d	External dermal exposure	0.0159 mg/kg bw/d
Systemic dermal exposure	0.001590 mg/kg bw/d	Systemic dermal exposure	0.001590 mg/kg bw/d
Body		Body	
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$		$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^{-2} \times DA) / BW$	
$(25 \times 0.09 \times 1 \times 10\%) / 60$		$(25 \times 0.09 \times 1 \times 1 \times 10\%) / 60$	
External dermal exposure	2.25 mg/person	External dermal exposure	2.25 mg/person
External dermal exposure	0.0375 mg/kg bw/d	External dermal exposure	0.0375 mg/kg bw/d
Systemic dermal exposure	0.003750 mg/kg bw/d	Systemic dermal exposure	0.003750 mg/kg bw/d
Head		Head	
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$		$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE^{-3} \times DA) / BW$	
$(4.8 \times 0.09 \times 1 \times 10\%) / 60$		$(4.8 \times 0.09 \times 1 \times 1 \times 10\%) / 60$	
External dermal exposure	0.432 mg/person	External dermal exposure	0.432 mg/person
External dermal exposure	0.0072 mg/kg bw/d	External dermal exposure	0.0072 mg/kg bw/d
Systemic dermal exposure	0.000720 mg/kg bw/d	Systemic dermal exposure	0.000720 mg/kg bw/d
Total systemic dermal exposure: $SDE_0 = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		Total systemic dermal exposure: $SDE_0 = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$	
Total external dermal exposure	22.086 mg/person	Total external dermal exposure	22.086 mg/person
Total external dermal exposure	0.3681 mg/kg bw/d	Total external dermal exposure	0.3681 mg/kg bw/d
Total systemic dermal exposure	0.03681 mg/kg bw/d	Total systemic dermal exposure	0.03681 mg/kg bw/d
Operators: Systemic inhalation exposure after application in vine			
Inhalation exposure during mixing/loading			
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$		$SIE_{OM} = (I_M \times AR \times A \times PPE^{-4} \times IA) / BW$	
$(0.05 \times 0.09 \times 1 \times 100\%) / 60$		$(0.05 \times 0.09 \times 1 \times 1 \times 100\%) / 60$	
External inhalation exposure	0.0045 mg/person	External inhalation exposure	0.0045 mg/person
External inhalation exposure	0.000075 mg/kg bw/d	External inhalation exposure	0.000075 mg/kg bw/d
Systemic inhalation exposure	0.000075 mg/kg bw/d	Systemic inhalation exposure	0.000075 mg/kg bw/d
Inhalation exposure during application			
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$		$SIE_{OA} = (I_A \times AR \times A \times PPE^{-4} \times IA) / BW$	
$(0.3 \times 0.09 \times 1 \times 100\%) / 60$		$(0.3 \times 0.09 \times 1 \times 1 \times 100\%) / 60$	
External inhalation exposure	0.027 mg/person	External inhalation exposure	0.027 mg/person
External inhalation exposure	0.00045 mg/kg bw/d	External inhalation exposure	0.00045 mg/kg bw/d
Systemic inhalation exposure	0.000450 mg/kg bw/d	Systemic inhalation exposure	0.000450 mg/kg bw/d
Total systemic inhalation exposure: $SIE_0 = SIE_{OM} + SIE_{OA}$		Total systemic inhalation exposure: $SIE_0 = SIE_{OM} + SIE_{OA}$	
Total external inhalation exposure	0.031500 mg/person	Total external inhalation exposure	0.031500 mg/person
Total external inhalation exposure	0.000525 mg/kg bw/d	Total external inhalation exposure	0.000525 mg/kg bw/d
Total systemic inhalation exposure	0.000525 mg/kg bw/d	Total systemic inhalation exposure	0.000525 mg/kg bw/d
Total systemic exposure: $SE_0 = SDE_0 + SIE_0$		Total systemic exposure: $SE_0 = SDE_0 + SIE_0$	
Total systemic exposure	2.24010 mg/person	Total systemic exposure	2.24010 mg/person
Total systemic exposure	0.037335 mg/kg bw/d	Total systemic exposure	0.037335 mg/kg bw/d
% of AOEL	0.4 %	% of AOEL	0.4 %

A 1.7 Operator, UK POEM, hand held high crop, no PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Hand-held rotary atomiser equipment (2.5 l tank). Outdoor, high level target		
Product	Vacciplant Fruits et Légumes	Active substance	laminarin
Formulation type	water-based	a.s. concentration	45 mg/ml
Dermal absorption from product	10 %	Dermal absorption from spray	10 %
Container	1 litre any closure		
PPE during mix/loading	None	PPE during application	None
Dose	2 l/ha	Work rate/day	1 ha
Application volume	100 l/ha	Duration of spraying	6 h

EXPOSURE DURING MIXING AND LOADING

Container size	1 litres
Hand contamination/operation	0.01 ml
Application dose	2 litres product/ha
Work rate	1 ha/day
Number of operations	40
Hand contamination	0.4 ml/day
Protective clothing	None
Transmission to skin	100 %
Dermal exposure to formulation	0.4 ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Hand-held rotary atomiser equipment (2.5 l tank). Outdoor, high level target		
Application volume	100 spray/ha		
Volume of surface contamination	50 ml/h		
Distribution	Hands	Trunk	Legs
	10%	65%	25%
Clothing	None	Permeable	Permeable
Penetration	100%	15%	20%
Dermal exposure	5	4.875	2.5 ml/h
Duration of exposure	6 h		
Total dermal exposure to spray	74.25 ml/day		

ABSORBED DERMAL DOSE

	Mix/load	Application
Dermal exposure	0.4 ml/day	74.25 ml/day
Concen. of a.s. product or spray	45 mg/ml	0.9 mg/ml
Dermal exposure to a.s.	18 mg/day	66.825 mg/day
Percent absorbed	10 %	10 %
Absorbed dose	1.8 mg/day	6.6825 mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01 ml/h
Duration of exposure	6 h
Concentration of a.s. in spray	0.9 mg/ml
Inhalation exposure to a.s.	0.054 mg/day
Percent absorbed	100 %
Absorbed dose	0.054 mg/day

PREDICTED EXPOSURE

Total absorbed dose	8.5365 mg/day
Operator body weight	60 kg
Operator exposure	0.142275 mg/kg bw/day

A 1.8 Operator, Dutch greenhouse model, hand held high and low crop, no PPE

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form	Vacciplant Fruits et Légumes		Application including mixing and loading	
a.s.	laminarin			
Parameter		Value	Unit	References, comments
MANUAL SPRAYING in greenhouses				
AR	Application rate	0.135	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
Inhalation Exposure			without PPE	
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Inhalation Exposure (without PPE)		0.135	mg a.s./ day	IE = SV x AR x A
Inhalation Exposure (with PPE)			with PPE	
	PPE-factor	1		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
Inhalation Exposure (with PPE)		0.135	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
Dermal Exposure			without PPE	
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Dermal Exposure		27	mg a.s./ day	DE = SV x AR x A
Dermal Exposure (with PPE)			with PPE	
	PPE-factor	10		Gloves + coverall: 10 (Dutch model)
Dermal Exposure (with PPE)		2.7	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	10	%	
	AOEL	600	mg a.s./ day	based on 60 kg bw
		Without PPE	With PPE	
Internal exposure		[mg a.s. / day]	[mg a.s. / day]	
	Inhalation	0.1350	0.1350	IE(int) = IE x (IA/100)
	Dermal	2.7000	0.2700	DE(int) = DE x (DA/100)
Total		2.8350	0.4050	sum
% AOEL				
	Inhalation	0	0	%AOEL = 100 x IE(int) / AOEL
	Dermal	0	0	%AOEL = 100 x DE(int) / AOEL
Total		0	0	sum

A 2.1 Bystander, EUROPOEM II

BYSTANDER EXPOSURE			EUROPOEM II MODEL	
form	laminarin		Outdoor application	
as	Vacciplant Fruits et Légumes			
Parameter		Value	Unit	References, comments
SPRAYING Process outdoor				
AR	Application rate	0.09	kg a.s. / ha	summary of intended uses
SV	Spray volume	100	L / ha	summary of intended uses
Inhalation Exposure				without PPE
	Default value			
SE	Surrogate Exposure Value	0.06	mL / m3	downwards: 0.03; upwards: 0.06 (EUROPOEM II)
T	Time of exposure	1	h	most probable estimation*
RR	Respiratory rate	1.25	m3 / h	default
	Inhalation Exposure	0.0675	mg a.s. / day	IE = (ARx1000/SV)xSExTxRR
Dermal Exposure				
	Default value			
SE	Surrogate Exposure Value	0.05		downwards: 0.005; upwards with leaves: 0.05; upward without leaves: 0.15 (EUROPOEM II)
SA	Surface area bystander	2	m2	EUROPOEM II
	Dermal Exposure	0.9	mg a.s./ day	DE = SE xSA X (AR x 100)
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	10	%	
	AOEL	600	mg a.s./ day	based on 60 kg bw
		Without PPE		
		[mg a.s./ day]		
Internal exposure				
	Inhalation	0.0675		IE(int) = IE x (IA/100)
	Dermal	0.090		DE(int) = DE x (DA/100)
	Total	0.158		sum
% AOEL				
	Inhalation	0.01		%AOEL = 100 x IE(int) / AOEL
	Dermal	0.02		%AOEL = 100 x DE(int) / AOEL
	Total	0.03		sum
*	One hour exposure is the default. It is referring to a potential 1 hour exposure, rather than the actual. It is based on the study design, and should not be lowered.			

A.2.2 Bystander/resident, German guidance paper

Estimation of bystander and resident exposure (adults and children)			
Active substance (a.s.)	laminarin		
Product	Vacciplant Fruits et Légumes		
Intended uses	High crops, tractor mounted (HCTM)		
Treated area per day (A)	8	ha/d	
Application rate (AR)	0.09	kg a.s./ha	
Number of applications (NA)	2		
1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).			
Dermal absorption (DA)	10	% (worst case, e.g. during application)	
Inhalation absorption (IA)	100	%	
Oral absorption (OA)	100	%	
Systemic AOEL	10	mg/kg bw/d	
Body weight (BW)	60	kg/person (adults)	
	16.15	kg/person (children)	
Distance between application and bystander or resident:			
Field crops not selected	1	m	
HCTM/HCHH:	Grapevine		
	3	m	
Home & garden not selected			
		m	
Drift deposit (D) for 1 appl. based on appl. technique and distance:	8.02 % (HCTM, 3 m)		
Drift deposit (D) for 2 appl. based on appl. technique and distance:	7.23 % (HCTM, 3 m)		
Airborne vapour concentration (ACv)	0.001	mg/m ³ 2)	
2) 1 µg/m ³ for semivolatile substances, i.e. vapour pressure (20 °C): $\geq 1 \times 10^{-6}$ - $< 5 \times 10^{-3}$ Pa; 15 µg/m ³ for volatile substances, i.e. vapour pressure (20 °C): $\geq 5 \times 10^{-3}$ Pa			

Estimation of bystander exposure during/after application in High crops, tractor mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):		Drift (D):	8.02 % (HCTM, 3 m)
Application rate (AR):	0.09 kg a.s./ha	Exposed Body Surface Area (BSA):	1 m ² (adults)
			0.21 m ² (children)
Body weight (BW):	60 kg/person (adults)	Specific Inhalation Exposure (I* _A):	0.018 mg/kg a.s. (6 hours, adults)
	16.15 kg/person (children)		0.01034 mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	10.00 % ('worst case')	Area Treated (A):	8 ha/d (based on High crops, tractor mounted (HCTM))
Inhalation absorption (IA):	100 %	Exposure duration (T):	5 min
AOEL:	10 mg/kg bw/d		

Bystander exposure towards laminarin					
Adults			Children		
Bystander: Dermal exposure after application in (via spray drift)					
SDE _B = (AR x D x BSA x DA) / BW (9 x 8.02% x 1 x 10%) / 60			SDE _B = (AR x D x BSA x DA) / BW (9 x 8.02% x 0.21 x 10%) / 16.15		
External exposure	0.7218	mg/person	External exposure	0.151578	mg/person
External exposure	0.01203	mg/kg bw/d	External exposure	0.00938563	mg/kg bw/d
Absorbed dose:	0.0012030	mg/kg bw/d	Absorbed dose:	0.0009386	mg/kg bw/d
Bystander: Inhalation exposure after application in					
SIE _B = (I* _A x AR x A x T x IA) / BW (0.000 / 360 x 0.09 x 8 x 5 x 100%) / 60			SIE _B = (I* _A x AR x A x T x IA) / BW (0.000 / 360 x 0.09 x 8 x 5 x 100%) / 16.15		
External exposure	0.00018	mg/person	External exposure	0.00010345	mg/person
External exposure	0.000003	mg/kg bw/d	External exposure	6.4055E-06	mg/kg bw/d
Absorbed dose:	0.0000030	mg/kg bw/d	Absorbed dose:	0.0000064	mg/kg bw/d
Total systemic exposure: SE _B = SDE _B + SIE _B			Total systemic exposure: SE _B = SDE _B + SIE _B		
Total systemic exposure (absorbed dose)	0.07236	mg/person	Total systemic exposure (absorbed dose)	0.01526125	mg/person
Total systemic exposure (absorbed dose)	0.0012060	mg/kg bw/d	Total systemic exposure (absorbed dose)	0.0009450	mg/kg bw/d
% of AOEL:	0.01	%	% of AOEL:	0.01	%

A 2.2 Bystander/resident, German guidance paper, cont'd

Estimation of resident exposure after application in High crops, tractor mounted (HCTM)

Input parameters considered for the estimation of resident exposure:

Intended use(s):		Drift (D):	7.23 % (HCTM, 3 m)
Application rate (AR):	0.09 kg a.s./ha	Transfer coefficient (TC):	7300 cm ² /h (adults)
			2600 cm ² /h (children)
Number of applications (NA):	2	Turf Transferable Residues (TTR):	5 %
Body weight (BW):	60 kg/person (adults)	Exposure Duration (H):	2 h
	16.15 kg/person (children)	Airborne Concentration of Vapour (ACV):	0,001 mg/m ³
Dermal absorption (DA):	10.00 % ('worst case')	Inhalation Rate (IR):	16.57 m ³ /d (adults),
Inhalation absorption (IA):	100 %		8.31 m ³ /d (children)
Oral absorption (OA)	100 %	Saliva Extraction Factor (SE):	50 %
AOEL	10 mg/kg bw/d	Surface Area of Hands (SA):	20 cm ²
		Frequency of Hand to Mouth (Freq):	20 events/h
		Dislodgeable foliar residues (DFR):	20 %
		Ingestion Rate for Mouthing of Grass/Day (IgR):	25 cm ² /d

Resident exposure towards laminarin

Adults			Children		
Residents: Dermal exposure after application in (via deposits caused by spray drift)					
$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$ (0.0009 x 2 x 7.23% x 5% x 7300 x 2 x 10%) / 60			$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$ (0.0009 x 2 x 7.23% x 5% x 2600 x 2 x 10%) / 16.15		
External exposure	0.0950022	mg/person	External exposure	0.0338364	mg/person
External exposure	0.00158337	mg/kg bw/d	External exposure	0.00209513	mg/kg bw/d
Absorbed dose:	0.0001583	mg/kg bw/d	Absorbed dose:	0.0002095	mg/kg bw/d
Residents: Inhalation exposure to vapour					
$SIE_R = (AC_V \times IR \times IA) / BW$ (0.001 x 16.57 x 100%) / 60			$SIE_R = (AC_V \times IR \times IA) / BW$ (0.001 x 8.31 x 100%) / 16.15		
External exposure	0.01657	mg/person	External exposure	0.00831	mg/person
External exposure	0.00027617	mg/kg bw/d	External exposure	0.00051455	mg/kg bw/d
Absorbed dose:	0.0002762	mg/kg bw/d	Absorbed dose:	0.0005146	mg/kg bw/d
Residents: Oral exposure (hand-to-mouth transfer)					
$SOE_H = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) /$ (0.0009 x 2 x 7.23% x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15			$SOE_H = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) /$ (0.0009 x 2 x 7.23% x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
External exposure	0.0026028	mg/person	External exposure	0.0026028	mg/person
External exposure	0.00016116	mg/kg bw/d	External exposure	0.00016116	mg/kg bw/d
Absorbed dose	0.0001612	mg/kg bw/d	Absorbed dose	0.0001612	mg/kg bw/d
Residents: Oral exposure (object-to-mouth transfer)					
$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$ (0.0009 x 2 x 7.23% x 20% x 25 x 100%) / 16.15			$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$ (0.0009 x 2 x 7.23% x 20% x 25 x 100%) / 16.15		
External exposure	0.0006507	mg/person	External exposure	0.0006507	mg/person
External exposure	4.0291E-05	mg/kg bw/d	External exposure	4.0291E-05	mg/kg bw/d
Absorbed dose	0.0000403	mg/kg bw/d	Absorbed dose	0.0000403	mg/kg bw/d
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$		
Total systemic exposure (absorbed dose)	0.02607022	mg/person	Total systemic exposure (absorbed dose)	0.01494714	mg/person
Total systemic exposure (absorbed dose)	0.0004345	mg/kg bw/d	Total systemic exposure (absorbed dose)	0.0009255	mg/kg bw/d
% of AOEL:	0.00	%	% of AOEL:	0.01	%

A 2.3 Bystander/resident, UK method PSD Guidance

Estimation of bystander and resident exposure (adults and children)			
Active substance (a.s.)	laminarin		
Product	Vacciplant Fruits et Légumes		
Intended uses	High crops, tractor mounted (HCTM)		
Treated area per day (A)	8	ha/d	
Application rate (AR)	0.09	kg a.s./ha	
Number of applications (NA)	2		
1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).			
Dermal absorption (DA)	10	% (worst case, e.g. during application)	
Inhalation absorption (IA)	100	%	
Oral absorption (OA)	100	%	
Systemic AOEL	10	mg/kg bw/d	
Body weight (BW)	60	kg/person (adults)	
	16.15	kg/person (children)	
Distance between application and bystander or resident:			
Field crops not selected	1	m	
HCTM/HCHH:	Grapevine		
	3	m	
Home & garden not selected			
Drift deposit (D) for 1 appl. based on appl. technique and distance:			8.02 % (HCTM, 3 m)
Drift deposit (D) for 2 appl. based on appl. technique and distance:			7.23 % (HCTM, 3 m)
Airborne vapour concentration (ACv)	0.001	mg/m ³ 2)	
2) 1 µg/m ³ for semivolatile substances, i.e. vapour pressure (20 °C): ≥ 1×10 ⁻⁶ - < 5×10 ⁻³ Pa; 15 µg/m ³ for volatile substances, i.e. vapour pressure (20 °C): ≥ 5×10 ⁻³ Pa			

Estimation of bystander exposure during/after application in High crops, tractor mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):		Drift (D):	8.02 % (HCTM, 3 m)
Application rate (AR):	0.09 kg a.s./ha	Exposed Body Surface Area (BSA):	1 m ² (adults)
			0.21 m ² (children)
Body weight (BW):	60 kg/person (adults)	Specific Inhalation Exposure (I* _A):	0.018 mg/kg a.s. (6 hours, adults)
	16.15 kg/person (children)		0.01034 mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	10.00 % ('worst case')	Area Treated (A):	8 ha/d (based on High crops, tractor mounted (HCTM))
Inhalation absorption (IA):	100 %	Exposure duration (T):	5 min
AOEL:	10 mg/kg bw/d		

Bystander exposure towards laminarin			
Adults		Children	
Bystander: Dermal exposure after application in (via spray drift)			
SDE _B = (AR x D x BSA x DA) / BW (9 x 8.02% x 1 x 10%) / 60		SDE _B = (AR x D x BSA x DA) / BW (9 x 8.02% x 0.21 x 10%) / 16.15	
External exposure	0.7218 mg/person	External exposure	0.151578 mg/person
External exposure	0.01203 mg/kg bw/d	External exposure	0.00938563 mg/kg bw/d
Absorbed dose:	0.0012030 mg/kg bw/d	Absorbed dose:	0.0009386 mg/kg bw/d
Bystander: Inhalation exposure after application in			
SIE _B = (I* _A x AR x A x T x IA) / BW (0,000 / 360 x 0.09 x 8 x 5 x 100%) / 60		SIE _B = (I* _A x AR x A x T x IA) / BW (0,000 / 360 x 0.09 x 8 x 5 x 100%) / 16.15	
External exposure	0.00018 mg/person	External exposure	0.00010345 mg/person
External exposure	0.000003 mg/kg bw/d	External exposure	6.4055E-06 mg/kg bw/d
Absorbed dose:	0.0000030 mg/kg bw/d	Absorbed dose:	0.0000064 mg/kg bw/d
Total systemic exposure: SE _B = SDE _B + SIE _B		Total systemic exposure: SE _B = SDE _B + SIE _B	
Total systemic exposure (absorbed dose)	0.07236 mg/person	Total systemic exposure (absorbed dose)	0.01526125 mg/person
Total systemic exposure (absorbed dose)	0.0012060 mg/kg bw/d	Total systemic exposure (absorbed dose)	0.0009450 mg/kg bw/d
% of AOEL:	0.01 %	% of AOEL:	0.01 %

A 2.3 Bystander/resident, UK method PSD Guidance, cont'd

Estimation of resident exposure after application in High crops, tractor mounted (HCTM)

Input parameters considered for the estimation of resident exposure:

Input parameters considered for the estimation of Residue exposure:					
Intended use(s):			Drift (D):	7.23	% (HCTM, 3 m)
Application rate (AR):	0.09	kg a.s./ha	Transfer coefficient (TC):	7300	cm ² /h (adults)
				2600	cm ² /h (children)
Number of applications (NA):	2		Turf Transferable Residues (TTR):	5	%
Body weight (BW):	60	kg/person (adults)	Exposure Duration (H):	2	h
	16.15	kg/person (children)	Airborne Concentration of Vapour (ACV):	0,001	mg/m3
Dermal absorption (DA):	10.00	% ('worst case')	Inhalation Rate (IR):	16.57	m ³ /d (adults),
Inhalation absorption (IA):	100	%		8.31	m ³ /d (children)
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE):	50	%
AOEL	10	mg/kg bw/d	Surface Area of Hands (SA):	20	cm ²
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm ² /d

Resident exposure towards laminarin

Adults			Children		
Residents: Dermal exposure after application in (via deposits caused by spray drift)					
$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$			$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$		
$(0.0009 \times 2 \times 7.23\% \times 5\% \times 7300 \times 2 \times 10\%) / 60$			$(0.0009 \times 2 \times 7.23\% \times 5\% \times 2600 \times 2 \times 10\%) / 16.15$		
External exposure	0.0950022	mg/person	External exposure	0.0338364	mg/person
External exposure	0.00158337	mg/kg bw/d	External exposure	0.00209513	mg/kg bw/d
Absorbed dose:	0.0001583	mg/kg bw/d	Absorbed dose:	0.0002095	mg/kg bw/d
Residents: Inhalation exposure to vapour					
$SIE_R = (AC_V \times IR \times IA) / BW$			$SIE_R = (AC_V \times IR \times IA) / BW$		
$(0.001 \times 16.57 \times 100\%) / 60$			$(0.001 \times 8.31 \times 100\%) / 16.15$		
External exposure	0.01657	mg/person	External exposure	0.00831	mg/person
External exposure	0.00027617	mg/kg bw/d	External exposure	0.00051455	mg/kg bw/d
Absorbed dose:	0.0002762	mg/kg bw/d	Absorbed dose:	0.0005146	mg/kg bw/d
			Residents: Oral exposure (hand-to-mouth transfer)		
			$SOE_H = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) /$		
			$(0.0009 \times 2 \times 7.23\% \times 5\% \times 50\% \times 20 \times 20 \times 2 \times 100\%) / 16.15$		
			External exposure	0.0026028	mg/person
			External exposure	0.00016116	mg/kg bw/d
			Absorbed dose	0.0001612	mg/kg bw/d
			Residents: Oral exposure (object-to-mouth transfer)		
			$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$		
			$(0.0009 \times 2 \times 7.23\% \times 20\% \times 25 \times 100\%) / 16.15$		
			External exposure	0.0006507	mg/person
			External exposure	4.0291E-05	mg/kg bw/d
			Absorbed dose	0.0000403	mg/kg bw/d
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$		
Total systemic exposure (absorbed dose)	0.02607022	mg/person	Total systemic exposure (absorbed dose)	0.01494714	mg/person
Total systemic exposure (absorbed dose)	0.0004345	mg/kg bw/d	Total systemic exposure (absorbed dose)	0.0009255	mg/kg bw/d
% of AOEL:	0.00	%	% of AOEL:	0.01	%

A 3.1 Worker, EUROPOEM II, re-entry field, no PPE

As a worst case, an application rate of 10 times 0.090 kg as/ha (no degradation) and a TC of 10000 cm²/h for vines (cf EFSA OPEX GD) is assumed.

WORKER EXPOSURE			EUROPOEM II MODEL	
form	Vacciplant Fruits et Légumes		Re-entry in the field	
a.s.	laminarin			
Parameter		Value	Unit	References, comments
Re-entry activities in the field				
AR	Application rate	0.9	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		8	hours / day	8 h
Inhalation Exposure				
	no model available	-		without PPE
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	1	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		216	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	10	%	
	PPE-factor dermal	5		gloves*
	AOEL	600	mg a.s./ day	based on 60 kg bw
		Without PPE	With PPE	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	21.600	4.320	DE(int) = DE x (DA/100)
	Total	21.600	4.320	sum
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	4	1	%AOEL = 100 x DE(int) / AOEL
	Total	4	1	sum

A 3.2 Worker, EUROPOEM II, re-entry greenhouse, no PPE

As a worst case, an application rate of 7 times 0.135 kg as/ha (no degradation) and a TC of 4500 cm²/h for tomato (vertical growth, significant contact with crop) is assumed.

WORKER EXPOSURE			EUROPOEM II & DUTCH MODEL	
form	Vacciplant Fruits et Légumes		Re-entry in greenhouses	
a.s.	laminarin			
Parameter		Value	Unit	References, comments
Re-entry activities in greenhouses				
AR	Application rate	0.945	kg a.s./ha	summary of intended uses
Worker				
Duration				
Tc	Cutting	4	hours / day	4h
Tsb	Sorting/ bundling	4	hours / day	4h
Tt	Total duration	8	hours / day	8h
Inhalation Exposure				
Task Specific Factor				without PPE
Surrogate value (indicative)				
TF	Cutting	0.1	(mg a.s./h)/(kg/ha)	Dutch model
TF	Sorting/ bundling	0.01	(mg a.s./h)/(kg/ha)	Dutch model
Inhalation Exposure				
	Cutting	0.378	mg a.s./ day	IE = AR x Tc x TF
	Sorting/ bundling	0.0378	mg a.s./ day	IE = AR x Tsb x TF
	Total	0.4158	mg a.s./ day	sum
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m ² /kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0.45	m ² / hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		102.06	mg a.s./ day	DE = DFR x AR x TC x Tt
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	10	%	
	PPE-factor inhalation	10		reduction factor* gloves**
	PPE-factor dermal	5		
	AOEL	600	mg a.s./ day	based on 60 kg bw
		Without PPE	With PPE	
		[mg a.s./ day]	[mg a.s./ day]	
Internal exposure				
	Inhalation	0.416	0.042	IE(int) = IE x (IA/100)
	Dermal	10.206	2.041	DE(int) = DE x (DA/100)
	Total	10.622	2.083	sum
% AOEL				
	Inhalation	0	0	%AOEL = 100 x IE(int) / AOEL
	Dermal	2	0	%AOEL = 100 x DE(int) / AOEL
	Total	2	0	sum